IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

CONCORDIA PHARMACEUTICALS INC., S.À.R.L., Plaintiff, v. WINDER LABORATORIES, LLC, and STEVEN PRESSMAN, Defendants. ---------- WINDER LABORATORIES, LLC, and STEVEN PRESSMAN, Counterclaim Plaintiffs, v. CONCORDIA PHARMACEUTICALS INC., S.À.R.L., Counterclaim Defendant.	Civil Action No. 2:16-cv-00004-RWS **JURY TRIAL DEMANDED**

DEFENDANTS' AND COUNTERCLAIM PLAINTIFFS' ANSWER TO FIRST AMENDED COMPLAINT AND COUNTERCLAIMS

For their answer under Federal Rule of Civil Procedure 8(b) to Plaintiff and Counterclaim Defendant Concordia Pharmaceuticals Inc., S.À.R.L.'s (Concordia) First Amended Complaint, Defendants and Counterclaim Plaintiffs Winder Laboratories, LLC, and Steven Pressman (collectively, Winder) state as follows:[1]

[1] On March 15, 2017, the Court granted Winder's motion to dismiss with prejudice as to Counts I and V of Concordia's First Amended Complaint; granted Winder's motion to dismiss as to Count VIII; and granted in part Winder's motion

NATURE AND BASIS OF ACTION

1. Winder admits that this action is brought under the Lanham Act, the Georgia Uniform Deceptive Practices Act, and Georgia common law. The remainder of the allegations in paragraph 1 consist of legal conclusions and contentions, to which a response is not required. To the extent a response is required, Winder denies the remaining allegations in paragraph 1.

2. Winder admits that Concordia seeks temporary, preliminary and permanent injunctive relief; actual damages; punitive damages; and recovery of costs and reasonable attorney fees. Winder admits that Concordia also seeks cancellation of Winder's U.S. Reg. No. 4,883,086 under 15 U.S.C. § 1119. Winder denies that Concordia is entitled to any relief and denies the remaining allegations in paragraph 2.

THE PARTIES

3. Winder admits that Concordia is a corporation organized under the laws of the Grand Duchy of Luxembourg but is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 3 and therefore denies them.

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to dismiss with prejudice as to Counts IV and VI. Docket No. 78. Winder's Answer omits the dismissed counts but preserves the original count and paragraph numbering in Concordia's First Amended Complaint.

4. Winder admits that it is a Georgia limited liability company with its principal office at 716 Patrick Industrial Lane, Winder, Georgia 30680. Winder also admits that it is the manufacturer and labeler of its Phenohytro product. Winder also admits that it may be served through its Registered Agent, Incorp Services Inc., at 2000 Riveredge Pkwy NW St. 885, Atlanta, Georgia 30328. Winder denies that it is presently the manufacturer and labeler of the B-Donna product, which is no longer listed on third-party drug databases, was never sold, and has been withdrawn from the market. Winder denies the remaining allegations in paragraph 4.

5. Winder admits that Steven Pressman is the managing member of Winder Laboratories, LLC. Winder denies the remaining allegations in paragraph 5.

JURISDICTION

6. Winder admits the allegations in paragraph 6.

7. Winder admits that venue is proper in this district under 28 U.S.C. § 1391. Winder denies that it infringes Concordia's Donnatal mark and denies the remaining allegations in paragraph 7.

8. Winder admits that this Court has personal jurisdiction over it. Winder denies that it infringes Concordia's Donnatal mark, denies that Concordia

has been harmed by Winder's conduct, and denies the remaining allegations in paragraph 8.

BACKGROUND FACTS

9. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 9 and therefore denies them.

10. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 10 and therefore denies them.

11. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 11 and therefore denies them.

12. Winder admits the allegations in paragraph 12.

13. The allegations in paragraph 13 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 13 and therefore denies them.

14. The allegations in paragraph 14 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 14 and therefore denies them.

15. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 15 and therefore denies them.

16. The allegations in paragraph 16 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 16 and therefore denies them.

17. The allegations in paragraph 17 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 17 and therefore denies them.

18. The allegations in paragraph 18 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 18 and therefore denies them.

19. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 19 and therefore denies them.

20. Winder denies the allegations in paragraph 20.

21. Winder denies the allegations in paragraph 21.

22. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 22 and therefore denies them.

THE DONNATAL MARK

23. Winder denies the allegations in paragraph 23.

24. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 24 and therefore denies them.

25. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 25 and therefore denies them.

26. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 26 and therefore denies them.

27. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 27 and therefore denies them.

28. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 28 and therefore denies them.

29. Winder admits that a document purporting to be a copy of U.S. Reg. No. 338,733 is attached as Exhibit A to Concordia's First Amended Complaint. Winder is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 29 and therefore denies them.

30. The allegations in paragraph 30 consist of legal conclusions to which no response is required. To the extent a response is required, Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 30 and therefore denies them.

31. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 31 and therefore denies them.

32. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 32 and therefore denies them.

WINDER'S CONDUCT

33. Winder admits that it is a Georgia-based manufacturer of drug products. Winder denies the remaining allegations in paragraph 33.

34. Winder denies the allegations in paragraph 34.

35. Winder admits the allegations in paragraph 35.

36. Winder denies the allegations in paragraph 36.

37. Winder denies the allegations in paragraph 37.

38. Winder admits that Concordia sued Winder in the Western District of Virginia in *Concordia Pharmaceuticals, Inc. v. Method Pharmaceuticals, LLC, et al.*, Docket No. 3:14-cv-00016. Winder is without sufficient knowledge or

information to form a belief about the truth of the remaining allegations in paragraph 38 and therefore denies them.

39. Winder denies the allegations in paragraph 39.

40. Winder admits that Winder was dismissed from the lawsuit referenced in paragraph 38 for lack of jurisdiction on July 1, 2015.

41. Winder denies the allegations in paragraph 41.

42. Winder admits the allegations in paragraph 42.

43. Winder admits the allegations in paragraph 43.

44. Winder admits that a document purporting to be a copy of the Certificate of Registration for the B-Donna mark is attached as Exhibit B to Concordia's First Amended Complaint. Winder also admits the remaining allegations in paragraph 44.

45. Winder admits that it did not obtain a National Drug Code ("NDC") number for any B-Donna product until December 2015. Winder denies the remaining allegations in paragraph 45.

46. Winder admits the allegations in paragraph 46.

47. Winder denies the allegations in paragraph 47.

48. Winder admits the allegations in paragraph 48.

49. Winder admits the allegations in paragraph 49.

50. Winder admits that a copy of B-Donna's Medi-Span listing is attached as Exhibit C to Concordia's First Amended Complaint. Winder also admits that listings for Winder's B-Donna product also appeared on Medi-Span and First Databank on or around January 2016. Winder denies the remaining allegations in paragraph 50.

51. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 51 and therefore denies them.

52. Winder admits that a document purporting to be a copy of an insurance formulary is attached as Exhibit D to Concordia's First Amended Complaint. Winder is without sufficient knowledge or information to form a belief about the truth of the remaining allegations in paragraph 52 and therefore denies them.

53. Winder admits that it has removed the listing for its B-Donna product from the FDA website, DailyMed. Winder denies the remaining allegations in paragraph 53.

54. Winder admits the allegations in paragraph 54.

55. Winder admits that a copy of Phenohytro's Medi-Span listing is attached as Exhibit E to Concordia's First Amended Complaint. Winder also admits that the Phenohytro product was listed with the FDA and on Medi-Span and

First Databank on or around February 2016. Winder denies the remaining allegations in paragraph 55.

56. Winder admits the allegations in paragraph 56.

57. Winder admits that a copy of a label and package insert for Phenohytro that purports to be from the DailyMed website is attached as Exhibit F to Concordia's First Amended Complaint. Winder also admits that the current label and package insert for Phenohytro is available on the DailyMed website. Winder denies the remaining allegations in paragraph 57.

58. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 58 and therefore denies them.

59. Winder admits that listings for its Phenohytro product appeared on Medi-Span and First Databank on or around February 2016. Winder denies the remaining allegations in paragraph 59.

60. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 60 and therefore denies them.

61. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 61 and therefore denies them.

62. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 62 and therefore denies them.

63. Winder denies the allegations in paragraph 63.

64. Winder denies the allegations in paragraph 64.

65. Winder denies the allegations in paragraph 65.

66. Winder admits the allegations in paragraph 66. Winder's B-Donna product, which is no longer listed on third-party drug databases, was never sold and has been withdrawn from the market.

67. Winder denies the allegations in paragraph 67.

68. Winder admits that package inserts for the B-Donna products existed and identified an elixir form of the B-Donna product. Winder also admits that no B-Donna product was sold. Winder denies the remaining allegations in paragraph 68.

69. Winder denies the allegations in paragraph 69.

70. Winder admits that more than one version of the package inserts for the Phenohytro products was developed. Winder denies the remaining allegations in paragraph 70.

71. Winder denies the allegations in paragraph 71.

72. Winder denies the allegations in paragraph 72.

73. Winder denies the allegations in paragraph 73.

74. Winder denies the allegations in paragraph 74.

75. Winder denies the allegations in paragraph 75.

76. Winder denies the allegations in paragraph 76.

77. Winder denies the allegations in paragraph 77.

78. Winder denies the allegations in paragraph 78.

79. Winder denies the allegations in paragraph 79.

80. Winder denies the allegations in paragraph 80.

81. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 81 and therefore denies them.

82. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 82 and therefore denies them.

83. Winder denies the allegations in paragraph 83.

84. Winder admits that listings of its B-Donna products and Phenohytro products on DailyMed, Medi-Span, and First Databank have been made available in this District. Winder denies the remaining allegations in paragraph 84.

85. Winder denies the allegations in paragraph 85.

86. Winder denies the allegations in paragraph 86.

87. Winder denies the allegations in paragraph 87.

88. Winder denies the allegations in paragraph 88.

89. Winder denies the allegations in paragraph 89.

90. Winder denies the allegations in paragraph 90.

91. Winder denies the allegations in paragraph 91.

92. Winder denies the allegations in paragraph 92.

93. Winder denies the allegations in paragraph 93.

94. Winder is without sufficient knowledge or information to form a belief about the truth of the allegations in paragraph 94 and therefore denies them.

95. Winder denies the allegations in paragraph 95.

COUNT I
FALSE ADVERTISING UNDER LANHAM ACT SECTION 43(A)(1)(B) (15 U.S.C. § 1125(A)(1)(B))

96-105. Count I was dismissed with prejudice by Order dated March 15, 2017. Accordingly, no response is required to these allegations. To the extent a response is required, Winder denies them.

COUNT II
CONTRIBUTORY FALSE ADVERTISING UNDER LANHAM ACT SECTION 43(A)(1)(B) (15 U.S.C. § 1125(A)(1)(B))

106. Winder restates and incorporates by reference the responses set forth in the paragraphs above.

107. Winder denies the allegations in paragraph 107.

108. Winder denies the allegations in paragraph 108.

109. Winder denies the allegations in paragraph 109.

110. Winder denies the allegations in paragraph 110.

111. Winder denies the allegations in paragraph 111.

112. Winder denies the allegations in paragraph 112.

113. Winder denies the allegations in paragraph 113.

114. Winder denies the allegations in paragraph 114.

115. Winder denies the allegations in paragraph 115.

116. Winder denies the allegations in paragraph 116.

117. Winder denies the allegations in paragraph 117.

COUNT III
TRADEMARK INFRINGEMENT UNDER LANHAM ACT SECTION 32
(15 U.S.C. § 1114)

118. Winder restates and incorporates by reference the responses set forth in the paragraphs above.

119. Winder denies the allegations in paragraph 119.

120. Winder denies the allegations in paragraph 120.

121. Winder denies the allegations in paragraph 121.

122. Winder denies the allegations in paragraph 122.

123. Winder denies the allegations in paragraph 123.

124. Winder denies the allegations in paragraph 124.

125. Winder denies the allegations in paragraph 125.

COUNT IV
UNFAIR COMPETITION UNDER LANHAM ACT SECTION 43(A)(1)(A)
(15 U.S.C. § 1125(A)(1)(A))

126. Winder restates and incorporates by reference the responses set forth in the paragraphs above.

127. Winder denies the allegations in paragraph 127.

128. Winder denies the allegations in paragraph 128.

129. Winder denies the allegations in paragraph 129.

130. Winder denies the allegations in paragraph 130.

131. Winder denies the allegations in paragraph 131.

132. Winder denies the allegations in paragraph 132.

COUNT V
COMMON LAW UNFAIR COMPETITION

133-137. Count V was dismissed with prejudice by Order dated March 15, 2017. Accordingly, no response is required to these allegations. To the extent a response is required, Winder denies them.

COUNT VI
GEORGIA UNIFORM DECEPTIVE PRACTICES ACT

138. Winder restates and incorporates by reference the responses set forth in the paragraphs above.

139. Winder admits that Concordia's First Amended Complaint restates some of the language of O.C.G.A. § 10-1-372. Winder denies the remaining allegations in paragraph 139.

140. Winder admits that O.C.G.A. § 10-1-373 provides that "[a] person likely to be damaged by a deceptive trade practice of another may be granted an injunction against it under the principles of equity and on terms that the court considers reasonable." Winder denies that Concordia is entitled to any relief and denies the remaining allegations in paragraph 140.

141. Winder denies the allegations in paragraph 141.

142. Winder denies the allegations in paragraph 142.

143. Winder denies the allegations in paragraph 143.

144. Winder denies the allegations in paragraph 144.

145. Winder denies the allegations in paragraph 145.

COUNT VII
COMMON LAW UNJUST ENRICHMENT

146. Winder restates and incorporates by reference the responses set forth in the paragraphs above.

147. Winder denies the allegations in paragraph 147.

148. Winder denies the allegations in paragraph 148.

149. Winder denies the allegations in paragraph 149.

150. Winder denies the allegations in paragraph 150.

COUNT VIII
TORTIOUS INTERFERENCE WITH CONTRACT OR BUSINESS RELATIONSHIPS

151-157. Count VIII was dismissed by Order dated March 15, 2017. Accordingly, no response is required to these allegations. To the extent a response is required, Winder denies them.

JURY DEMAND

Winder admits that Concordia demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Winder denies that Concordia is entitled to any relief and denies any remaining allegations in the Prayer for Relief.

Winder denies any remaining allegation in the First Amended Complaint that has not previously been addressed in this Answer.

AFFIRMATIVE DEFENSES

Further responding to the First Amended Complaint and as additional defenses thereto, Winder asserts the following affirmative defenses, without admitting any allegations of the First Amended Complaint not previously admitted.

FIRST AFFIRMATIVE DEFENSE
(First Amendment)

1. Concordia's request for relief is barred by the free speech clause of the First Amendment to the United States Constitution, U.S. Const. amend. I, cl. 2.

SECOND AFFIRMATIVE DEFENSE
(Preclusion and Preemption)

2. Concordia's request for relief is barred because Concordia's claims are precluded and preempted by federal law, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

3. Concordia has failed to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6) because Concordia's First Amended Complaint fails to identify any false or misleading statements or misrepresentations, fails to allege any facts demonstrating trademark infringement, and fails to allege any facts in support of the various elements of its state law claims.

FOURTH AFFIRMATIVE DEFENSE
(No False Statement)

4. Concordia's request for relief is barred because the representations and actions alleged are not false or misleading.

FIFTH AFFIRMATIVE DEFENSE
(No Deception)

5. Concordia's request for relief is barred because the representations and actions alleged do not mislead or deceive or have the capacity to mislead or deceive a substantial portion of the relevant purchasing public.

SIXTH AFFIRMATIVE DEFENSE
(No Materiality)

6. Concordia's request for relief is barred because the representations and actions alleged do not materially affect a substantial portion of the relevant purchasing public's purchasing decisions.

SEVENTH AFFIRMATIVE DEFENSE
(No Reliance)

7. Concordia's request for relief is barred because a substantial portion of the relevant purchasing public did not rely on the representations and actions alleged.

EIGHTH AFFIRMATIVE DEFENSE
(No Injury)

8. Concordia's request for relief is barred because the representations and actions alleged do not result in any actual or likely injury to Concordia.

NINTH AFFIRMATIVE DEFENSE
(No Intent)

9. Concordia's request for relief is barred because the representations and actions alleged are not intended to mislead or deceive a substantial portion of the relevant purchasing public.

TENTH AFFIRMATIVE DEFENSE
(No Infringement)

10. Concordia's request for relief is barred because Winder's registered B-Donna mark is not a reproduction, counterfeit, copy, or colorable imitation of any allegedly enforceable trademark owned by Concordia.

11. Concordia's request for relief is barred because Winder is not infringing, has not infringed, and is not liable for infringing any allegedly enforceable trademark owned by Concordia, either directly or by inducing others to infringe or by contributing to infringement by others.

ELEVENTH AFFIRMATIVE DEFENSE
(No Likelihood of Confusion)

12. Concordia's request for relief is barred because Winder's use of its registered B-Donna mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services is not likely to cause confusion, cause mistake, or deceive.

TWELFTH AFFIRMATIVE DEFENSE
(No Benefit Conferred)

13. Concordia's request for relief is barred because it has not conferred, and Winder has not gained, any benefit for which compensation is due or for which any compensation is unjust.

THIRTEENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

14. Concordia's request for relief is barred by the equitable doctrine of unclean hands because Concordia has made demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's product Phenohytro to Winder's potential and existing customers and caused Winder to lose both sales of its Phenohytro product and customers.

FOURTEENTH AFFIRMATIVE DEFENSE
(Failure to Mitigate)

15. Concordia's request for relief is barred because it has failed to mitigate its damages, if any, and is therefore not entitled to recover any damages.

FIFTEENTH AFFIRMATIVE DEFENSE
(No Irreparable Harm)

16. Concordia's request for injunctive relief is barred because it has an adequate remedy at law and cannot show that it has suffered or will suffer irreparable harm.

SIXTEENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

17. Concordia's request for relief is barred because it cannot prove that this is an exceptional case under 15 U.S.C. § 1117(a) or that it is entitled to any damages award or any award of costs, fees, or interest.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Essential Facilities)

18. Concordia's request for relief is barred because it cannot use the drug database listings, which are essential to the marketing, promotion, and sale of drug products, to block competitors from entering the market.

EIGHTEENTH AFFIRMATIVE DEFENSE
(Public Policy)

19. Concordia's request for relief is barred because its unlawful and anti-competitive conduct is against public policy.

NINETEENTH AFFIRMATIVE DEFENSE
(Superseding Cause)

20. Concordia's request for relief is barred because any injury it suffered was caused by separate and superseding causes or by its own conduct.

RESERVED DEFENSES

Winder reserves all affirmative defenses under Federal Rule of Civil Procedure 8(c), the Lanham Act, the Georgia Uniform Deceptive Trade Practices Act, Georgia common law, and any other defenses, at law or equity, which may

now exist or in the future may be available based on discovery and further factual investigation in this case.

COUNTERCLAIMS

PARTIES

1. Counterclaim plaintiff Winder Laboratories, LLC (Winder), is a Georgia limited liability company with its principal place of business at 716 Patrick Industrial Lane, Winder, Georgia 30680.

2. Counterclaim plaintiff Steven Pressman (Winder, together with counterclaim plaintiff Winder Laboratories, LLC) is a California resident and is the managing member of Winder.

3. Counterclaim defendant Concordia Pharmaceuticals Inc. (Concordia) is a corporation organized under the laws of the Grand Duchy of Luxembourg and a subsidiary of Concordia Healthcare Corp., a Canadian pharmaceutical company.

THE CONTROVERSY

4. Concordia has sued Winder for contributory false advertising, trademark infringement, unfair competition, violations of the Georgia Uniform Deceptive Trade Practices Act, and unjust enrichment under Georgia common

law.[2] Winder denies Concordia's allegations and asserts various defenses, affirmative defenses, and responses under Federal Rule of Civil Procedure 12 to the allegations in Concordia's First Amended Complaint. Those denials and assertions are incorporated by reference into these counterclaims.

5. In addition to its lawsuit, Concordia has embarked on a campaign to unlawfully interfere with Winder's potential and existing contractual and business relationships by, among other things, sending letters to potential purchasers of its Phenohytro product that are riddled with false accusations about Winder and Phenohytro. These letters harmed Winder by delaying Phenohytro's entrance in the market and discouraging purchases of Phenohytro by Winder's potential and existing customers.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over Winder's counterclaims under 28 U.S.C. §§ 1331 (federal question), 1367 (supplemental jurisdiction), 1338 (trademarks), and 2201 (declaratory judgment).

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[2] On March 15, 2017, the Court dismissed Concordia's claims for false advertising under the Lanham Act and common law unfair competition with prejudice; dismissed in part Concordia's claims for unfair competition under the Lanham Act and violations of the Georgia Uniform Deceptive Trade Practices Act with prejudice; and dismissed Concordia's claim for tortious interference. Docket No. 78.

7. This Court may declare the rights of the parties and grant the relief requested under 28 U.S.C §§ 2201 and 2202. Winder is entitled to seek declaratory judgment that its registered B-Donna mark does not infringe Concordia's Donnatal mark.

8. Venue is proper in this judicial district for these counterclaims under 28 U.S.C. § 1391.

BACKGROUND

9. This lawsuit involves competition in the market for drug products containing a combination of phenobarbital and belladonna alkaloids (PBA) for the treatment of irritable bowel syndrome.

10. For more than 35 years, Concordia and its predecessors have enjoyed a monopoly on the manufacture, marketing, and sale of PBA products under the name "Donnatal."

11. Concordia brought this lawsuit for the sole purpose of protecting its market position and excluding Winder, a direct competitor, from the marketplace.

The Parties' Products

12. Like Concordia, Winder manufactures, markets, and sells a PBA product for the treatment of irritable bowel syndrome under the name "Phenohytro."

13. Because Winder's Phenohytro product combines phenobarbital belladonna alkaloids, and such drug formulations were marketed before the enactment of the Food, Drug, and Cosmetic Act (FDCA) in 1938, it is exempt from the FDCA's "new drug" approval requirement. *See* 21 U.S.C. §§ 321(p)(1), 355.

14. At one time, Winder also manufactured a PBA product under the name "B-Donna," a name derived by shortening one of the product's active ingredients, **b**ella**donna** alkaloids.

15. Although B-Donna was available for sale beginning on December 30, 2015, Winder never sold any units of B-Donna and withdrew it from the market in early 2016. The withdrawal of B-Donna was a business decision that was unrelated to any regulatory issue.

16. Winder's B-Donna and Phenohytro products contain the same active ingredients in the same strengths and the same dosage form, and have the same route of administration, as Donnatal, making Winder's and Concordia's products "pharmaceutically equivalent."

17. Food and Drug Administration (FDA) regulations require that labels on drug products list active ingredients, strengths, usage, and dosage form. *See* 21 U.S.C. § 352(e); 21 C.F.R. §§ 201.10, 201.51(a).

18. Because Winder's B-Donna and Phenohytro products and Concordia's Donnatal product are pharmaceutically equivalent, the information on the products' labels is necessarily the same.

The Orange Book

19. As pharmaceutical equivalents, Winder's B-Donna and Phenohytro products and Concordia's Donnatal product are "identical, related, and similar" (IRS) to the FDA-approved drugs reviewed by the National Academy of Sciences-National Research Council (the Academy) and determined to be "possibly effective" for the treatment of irritable bowel syndrome. Thus, the products are subject to the FDA's 1975 Drug Efficacy Study Implementation (DESI) notice applying the Academy's "possibly effective" determination to all "identical, related, and similar" drugs. *See* 40 Fed. Reg. 52,644, 52,646 (1975).

20. The 1975 DESI notice lists the approved drugs that were reviewed by the Academy and specifically identifies Donnatal as an unapproved drug not reviewed by the Academy or by the FDA.

21. Donnatal, like Winder's products B-Donna and Phenohytro, has never been approved for effectiveness by the FDA and is not listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, known commonly as the "Orange Book."

22. The Orange Book contains drugs approved by the FDA and their approved generic equivalents.

23. Because Donnatal, B-Donna, and Phenohytro have never been approved for effectiveness by the FDA and are not listed in the Orange Book, none can be "A-rated" by the FDA.

24. On information and belief, pharmacists generally do not consult the Orange Book when deciding whether to substitute drugs for those prescribed by physicians.

Medi-Span and First Databank

25. To market drug products, manufacturers provide information about the active ingredients in those products and pricing to third-party drug databases Medi-Span and First Databank, which are available only by subscription.

26. Listings on Medi-Span and First Databank are necessary to market and promote drug products, in part because unlisted drugs will not be covered by insurance companies. Thus, a drug that cannot be listed on Medi-Span and First Databank is effectively blocked from the market place.

27. Other industry participants in turn rely on Medi-Span and First Databank to group pharmaceutically equivalent products.

28. Medi-Span and First Databank use the listing of active ingredients and strengths on drug products' labels to group pharmaceutically equivalent products; thus, pharmaceutical equivalents like B-Donna, Phenohytro, and Donnatal, whose labels necessarily contain the same information as required by FDA regulation, are grouped by Medi-Span and First Databank as pharmaceutical equivalents.

29. Grouping of products by Medi-Span and First Databank signifies only pharmaceutical equivalence; it does not signify bioequivalence, therapeutic equivalence, FDA approval, rating by the FDA, or substitutability.

30. On information and belief, pharmacists generally do not consult Medi-Span and First Databank (which are available by subscription only) when deciding whether to substitute drugs for those prescribed by physicians.

31. On April 29, 2016, Concordia sued Medi-Span for false advertising and contributory false advertising under the Lanham Act and tortious interference under Indiana law. *Concordia Pharmaceuticals, Inc. v. Clinical Drug Information, LLC*, No. 1:16-cv-00971-WTL-DML (S.D. Ind.). After the parties briefed Medi-Span's motion to dismiss but before it could be decided, Concordia voluntarily dismissed this lawsuit.

32. On May 3, 2016, Concordia also sued First Databank for false advertising and contributory false advertising under the Lanham Act and tortious

interference under New York law. *Concordia Pharmaceuticals Inc., S.A.R.L. v. First Databank, Inc.*, No. 1:16-cv-03307-PAE (S.D.N.Y.). After First Databank filed a motion to dismiss, Concordia filed an amended complaint. The parties then sought two extensions of the deadline for First Databank's response to Concordia's amended complaint, explaining that Concordia was "involved in discussions with the [FDA] which may be relevant to this case," "may clarify the issues to be presented to the Court," and "may simplify the issues to be presented to the Court." *See* attached Exhibit 1 (Aug. 10 and 31, 2016 extension requests). On October 4, the parties submitted their stipulation of voluntary dismissal.

Prescription Drug Substitution

33. In the majority of U.S. states, pharmacists are not authorized to substitute drugs that are not A-rated for those prescribed by physicians without the physicians' permission.

34. Other states, however, do not require that products be A-rated, or even approved by the FDA, for substitution. These states, including the state of Georgia, permit pharmacists to substitute unapproved, non-A-rated drugs, provided that the drugs are at least pharmaceutically equivalent. *See* O.C.G.A. §§ 26–4–81(a), 26–4–5(27).

35. When physicians prescribe Donnatal, Phenohytro may be substituted with the physicians' permission in a majority of states, and may be substituted by pharmacists in Georgia and other states.

36. In all states, it is the legal responsibility of the pharmacists filling the physicians' prescriptions, relying on the information available to them, to make decisions about whether to substitute drugs for those prescribed by the physicians.

37. Pharmaceutical equivalence and any resulting grouping in the databases is not, alone, sufficient for pharmacists, physicians, wholesalers, insurance companies, third-party payors, or others to make decisions about the substitutability of any drug product for another; rather, all of these market participants, and pharmacists in particular, require additional information to make substitutability decisions.

38. Medi-Span and First Databank do not provide that additional information, and what information is available to pharmacists is also subject to the control and decision-making of those who input information into prescription management software, including pharmacies, wholesalers, and insurance companies.

39. When making the decisions to substitute drugs for those prescribed by physicians, pharmacists rely on their pharmacies' prescription management

software specifically, and others in the pharmaceutical industry generally, to make decisions about substitution, decisions that are ultimately the responsibility of the pharmacists under state law.

Winder's Listings

40. In January 2016, Winder listed its B-Donna product with the U.S. Food and Drug Administration, the National Library of Medicine DailyMed website, and the third-party drug databases Medi-Span and First Databank.

41. The information Winder provided to Medi-Span and First Databank about its B-Donna product attached as Exhibit 2 explicitly disclaims FDA approval: "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA."

42. The listing for B-Donna on Medi-Span attached as Exhibit 3 indicated in the "Marketing Category" field that the product was "UNAPPROVED."

43. The listing for B-Donna on Medi-Span also indicated that "the labeler" was "Winder Laboratories." *See* Exhibit 3.

44. The "therapeutic equivalence evaluation" ("TEE") field included in the B-Donna listing on Medi-Span also described the product as "NR-Not Rated," indicating that the FDA had not rated the product as therapeutically equivalent to any other product. *See* Exhibit 3.

45. Winder did not sell any units of B-Donna and withdrew the product from the market in early 2016. The listings of B-Donna with the U.S. Food and Drug Administration, the National Library of Medicine DailyMed website, Medi-Span, and First Databank have been taken down.

46. In February 2016, Winder listed Phenohytro with the U.S. Food and Drug Administration, the National Library of Medicine DailyMed website, and Medi-Span and First Databank.

47. The information Winder provided to Medi-Span and First Databank about its Phenohytro product attached as Exhibit 4 explicitly disclaims FDA approval: "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA."

48. The listing for Phenohytro on the DailyMed website of the National Library of Medicine attached as Exhibit 5 explicitly indicates that it is "unapproved."

49. The listing for Phenohytro on Medi-Span attached as Exhibit 6 indicates in the "Marketing Category" field that the product is "UNAPPROVED."

50. The listing for Phenohytro on Medi-Span also indicates that "the labeler" is "Winder Laboratories." *See* Exhibit 6.

51. The "therapeutic equivalence evaluation" ("TEE") field included in the Phenohytro listing on Medi-Span also describes the product as "NR-Not Rated," indicating that the FDA has not rated the product as therapeutically equivalent to any other product. *See* Exhibit 6.

Concordia's Tortious Interference and False Representations

52. In early 2016, as soon as Winder listed its products with Medi-Span and First Databank, Concordia began a campaign to interfere in Winder's contractual and business relationships with its potential and existing customers, including wholesalers, distributors, and pharmacy chains. These relationships are vital to the distribution and sale of its products.

53. Concordia's campaign includes, but on information and belief is not limited to, letters that it sent to the three largest drug wholesalers in the United States, McKesson, Cardinal, and ABC, as well as numerous retail pharmacy chains including Wal-Mart, Publix, Walgreens, HEB, CVS, Rite Aid, Kroger, Schnucks, Super Value, and Giant. Copies of Concordia's letters, produced by Concordia in discovery related to Concordia's unsuccessful motions for a preliminary injunction, are attached as Exhibit 7.

54. Concordia's letters contain many demonstrably false statements, misrepresentations, and misstatements of law, which caused Winder's potential

and existing customers to delay purchases of Phenohytro and delayed the product's entry in the market.

55. For example, Concordia's letters make the baseless accusations that Winder is marketing "illegal drug products under the name Phenohytro, which Winder claims are generic versions" of Donnatal and that Winder "has previously tried to launch an unlawful drug product that claimed to be a generic version" of Donnatal. Concordia's letters also falsely state that Phenohytro is "unsafe" and that the letter recipients' patients' safety is at "risk." *See* Exhibit 7.

56. Contrary to Concordia's letters, Winder's products are legal, Winder's marketing, promotion, and sales of its products was and is legal and wholly legitimate, and Winder has never marketed or promoted any of its products as "generic versions" of Donnatal.

57. In the fall of 2015, Winder secured a commitment from CVS to purchase Phenohytro. After receiving Concordia's letter in the spring of 2016, however, CVS suspended its contract with Winder. That decision, in turn, affected Winder's business relationship with Cardinal, among other wholesalers, distributors, and pharmacies.

58. Because of Concordia's letters, Winder's other potential customers have delayed their purchases of Phenohytro.

59. Concordia's predatory tactics, including but not limited to its letters, harmed Winder by delaying Phenohytro's entrance in the market and discouraging purchases of Phenohytro by Winder's potential and existing customers.

60. Concordia's predatory tactics, including but not limited to its letters, harmed Winder by preventing it from retaining existing customers or obtaining new ones.

COUNT I
(Declaratory Judgment of No Infringement)

61. Winder incorporates by reference the allegations set forth in paragraphs 1 through 60 above.

62. Winder's registered B-Donna mark is merely suggestive of an active ingredient found in all PBA products, including Winder's B-Donna and Phenohytro products and Concordia's Donnatal product: **b**ella**donna** alkaloids.

63. Winder's registered B-Donna mark is not a reproduction, counterfeit, copy, or colorable imitation of any allegedly enforceable trademark owned by Concordia.

64. Winder's use of its registered B-Donna mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services is not and was not likely to cause confusion, cause mistake, or deceive.

65. Winder's use of its registered B-Donna mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services is not and was not intended to cause confusion, cause mistake, or deceive.

66. Winder's use of its registered B-Donna mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services is not and was not intended to gain any competitive advantage by associating any goods or services with any allegedly enforceable trademark owned by Concordia.

67. Winder is entitled to declaratory judgment that it is not infringing, has not infringed, and is not liable for infringing any allegedly enforceable trademark owned by Concordia, either directly or by inducing others to infringe or by contributing to infringement by others.

COUNT II
(False Advertising)

68. Winder incorporates by reference the allegations set forth in paragraphs 1 through 67 above.

69. Winder and Concordia are direct competitors in the market for the sale of PBA products.

70. Concordia has used and, on information and belief, continues to use false and misleading descriptions and representations of fact in commercial advertising and promotion about the nature, characteristics, and qualities of its

products and Winder's products. Those false and misleading descriptions and representations of fact have deceived or have the tendency to deceive a substantial portion of the relevant purchasing public.

71. As alleged above, Concordia's letters to purchasers and potential purchasers of PBA products, including drug wholesalers, distributors, and retail pharmacy chains contain numerous demonstrably false statements, misrepresentations, and misstatements of law, which caused Winder's potential and existing customers to delay purchases of Phenohytro and delayed the product's entry in the market. These false and misleading statements by Concordia constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

72. Concordia causes, and has caused, its false and misleading advertising to enter interstate commerce, including by making false and misleading statements in letters to consumers throughout the United States.

73. Concordia's false and misleading statements are material in that they have and are likely to influence consumers' purchasing decisions and because they relate to inherent qualities or characteristics of Winder's products.

74. As a direct and proximate result of the wrongful acts of Concordia alleged above, Winder has suffered, and will continue to suffer, substantial damage

to its business reputation, goodwill, and market share, as well as loss of profits in an amount not yet ascertained.

75. Concordia's false advertising will continue to harm Winder, causing irreparable injury for which there is no adequate remedy at law, unless permanently enjoined by this Court under 15 U.S.C. § 1116.

76. Winder is entitled to enhanced monetary damages of up to three times the amount of Winder's actual damages or Concordia's profits resulting from Concordia's false advertising, in an amount to be proven at trial, and the costs of the action under 15 U.S.C. § 1117(a).

77. Winder is also entitled to an accounting of Concordia's profits resulting from its Lanham Act violations.

78. Upon information and belief, Concordia's false advertising is willful, knowing, calculated to deceive, and was undertaken in bad faith. As a result, this Court should determine that this is an exceptional case and award Winder its attorneys' fees and costs incurred in prosecuting this action under 15 U.S.C. § 1117(a).

COUNT III
(Tortious Interference with Contractual Relationships)

79. Winder incorporates by reference the allegations set forth in paragraphs 1 through 78 above.

80. Concordia is aware of Winder's contractual relationships with wholesalers, distributors, and pharmacy chains, which are vital to the distribution and sale of Phenohytro.

81. With malicious intent to injure Winder by interfering with its contractual relationships, Concordia began a campaign in early 2016 in which it perpetuated demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

82. Concordia's wrongful and intentional conduct included letters to wholesalers, distributors, and pharmacy chains containing demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

83. Concordia's letters interfered with Winder's contractual relationships, caused Winder's existing customers to delay purchases of Winder's Phenohytro product, and delayed the product's entry in the market.

84. Concordia's wrongful and intentional conduct is not privileged and is actionable under Georgia law.

85. Concordia's wrongful and intentional conduct has caused damage to Winder in the form of lost sales, lost profits, and lost customers.

COUNT IV
(Tortious Interference with Business Relationships)

86. Winder incorporates by reference the allegations set forth in paragraphs 1 through 85 above.

87. Concordia is aware of Winder's business relationships with wholesalers, distributors, and pharmacy chains, which are vital to the distribution and sale of Phenohytro.

88. With malicious intent to injure Winder by interfering with its business relationships, Concordia began a campaign in early 2016 in which it perpetuated demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

89. Concordia's wrongful and intentional conduct included letters to wholesalers, distributors, and pharmacy chains containing demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

90. Concordia's letters interfered with Winder's business relationships, caused Winder's potential and existing customers to delay purchases of Winder's Phenohytro product, and delayed the product's entry in the market.

91. Concordia's wrongful and intentional conduct is not privileged and is actionable under Georgia law.

92. Concordia's wrongful and intentional conduct has caused damage to Winder in the form of lost sales, lost profits, and lost customers.

COUNT V
(Violations of the Georgia Uniform Deceptive Trade Practices Act)

93. Winder incorporates by reference the allegations set forth in paragraphs 1 through 92 above.

94. The Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372(a)(8), provides that "[a] person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he . . . [d]isparages the goods, services, or business of another by false or misleading representation of fact."

95. Concordia began a campaign in early 2016 in which it perpetuated demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

96. Concordia's wrongful and intentional conduct included letters to wholesalers, distributors, and pharmacy chains containing demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

97. Concordia's letters disparaged Winder's Phenohytro product, caused Winder's potential and existing customers to delay purchases of Winder's Phenohytro product, and delayed the product's entry in the market.

98. Concordia's wrongful and intentional conduct is not privileged and is actionable under Georgia law.

99. Concordia's wrongful and intentional conduct has caused damage to Winder in the form of lost sales, lost profits, and lost customers.

COUNT VI
(Common Law Unfair Competition)

100. Winder incorporates by reference the allegations set forth in paragraphs 1 through 99 above.

101. Concordia began a campaign in early 2016 in which it perpetuated demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

102. Concordia's wrongful and intentional conduct included letters to wholesalers, distributors, and pharmacy chains containing demonstrably false statements, misrepresentations, and misstatements of law about Winder and Winder's Phenohytro product.

103. Concordia's wrongful and intentional conduct unfairly hampered Winder's efforts to market, promote, and sell its Phenohytro product to both existing and potential customers.

104. Concordia's wrongful and intentional conduct is not privileged and is actionable under Georgia law.

105. Concordia's wrongful and intentional conduct has caused damage to Winder in the form of lost sales, lost profits, and lost customers.

JURY DEMAND

Winder demands a trial by jury.

PRAYER FOR RELIEF

Wherefore, Winder respectfully requests that the Court enter judgment for Winder and against Concordia and grant the following relief:

(a) A declaration that Winder's registered B-Donna mark does not infringe any allegedly enforceable trademark owned by Concordia;

(b) An order permanently enjoining Concordia from using false and misleading descriptions and representations of fact in commercial advertising and promotion about the nature, characteristics, and qualities of Winder's products and from interfering with Winder's contractual and business relationships;

(c) Compensatory damages in an amount to be proven at trial;

(d) Punitive damages;

(e) A declaration that Concordia is not entitled to damages, interests, costs, or any other relief associated with this action;

(f) A declaration that this case is exceptional and Winder is entitled to an award of reasonable attorney fees and costs under 15 U.S.C. § 1117(a);

(g) An award of reasonable attorney fees and costs under 15 U.S.C. § 1117(a); and

(h) Any other relief this Court deems just and proper.

Respectfully submitted this 29th day of March, 2017.

/s/ *Joshua Counts Cumby*

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LOCAL RULE 7.1 CERTIFICATION OF COMPLAINCE

I hereby certify that the foregoing has been prepared in 14-point Times New Roman font in accordance with Local Rule 5.1(C).

Dated: March 29, 2017.

/s/ *Joshua Counts Cumby*
Joshua Counts Cumby, *pro hac vice*

CERTIFICATE OF SERVICE

I hereby certify that on March 29, 2017, I electronically filed this Answer to First Amended Complaint and Counterclaims with the Clerk of the Court using the CM/ECF system, which will send notification of the filing to all counsel of record.

/s/ *Joshua Counts Cumby*

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